AUG 0 6 2002

K022065

SUMMARY OF SAFETY AND EFFECTIVENESS
Sintea Biotech Traumafix System

Mechanical tests of the Sintea Biotech Traumafix System demonstrate that the device is safe and effective for its intended use. The referenced predicate device, the Lima-Lto External Circular Stabilizer (ECS), is in fact the same device as the Sintea Biotech Traumafix System, and therefore the favorable clinical performance of the Lima ECS provides additional confirmation that the Sintea Biotech Traumafix System is safe and effective for its intended use. The Sintea Biotech Traumafix System and the Lima-Lto ECS are similar in that:

- the devices have the same intended use and indications for use
- the implanted portion of the devices is made of the same material
- the external portion of the devices is made of the same material
- the mode of fixation of the devices is identical
- the devices have similar form, function, components, instruments, geometry, features and packaging
- the devices have the same labeling and sterilization method

The use of QSR-based process controls, testing standards, material standards and similarities to the predicate device establish that the Sintea Biotech Traumafix System is equivalent to the Lima-Lto ECS and that it is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Sintea Biotech, Inc.
Marianne Grunwaldt
407 Lincoln Road, Suite 10L
Miami Beach, Florida 33139

Re: K022065
Trade Name: Sintea Biotech Traumafix System, Model TFX. 00.00.X
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JEC
Dated: July 19, 2002
Received: July 22, 2002

Dear Ms. Grunwaldt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address: http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022065

Device Name: Sintea Biotech Traumafix System

Indications For Use:

The Sintea Biotech Traumafix System is indicated for use in the following conditions:

- Fracture
- Limb lengthening
- Reconstruction
- Traction

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022065

(Optional Format 3-10-98)